## REMARKS

This response addresses the non-final Office Action dated, March 14, 2008.

### I. Claim Status

Currently, claims 1-25 are pending. Claims 18-24 have been withdrawn from consideration, and claims 1-17, and 25 stand rejected.

Applicant requests that the Examiner enter amended claims 1, 2, 25; and new claim 26. Applicant believes that the claims are now in condition for allowance, and notification to that effect is respectfully requested. The following amendments contain no new matter and are supported throughout the specification as filed. This listing replaces all prior versions, and listings of claims in the application.

### II. Interview Summary

The Applicant acknowledges with appreciation the opportunity to conduct a telephonic interview with the Examiner. The Interview took place on June 25, 2008 and the remaining grounds of rejection were discussed. The details of the Interview are set forth below, in detail, in comments traversing the present rejections.

### III. Claim Rejections

#### 1. 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of claims 1-17 and 25 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and enablement requirements. Specifically, the Examiner states that one of skill in the art would not recognize from the disclosure that applicant was in possession of the claimed genus and that members of the genus cannot be produced without undue experimentation.

The Examiner incorrectly states that only a single species of the claimed genus that is within the scope of the claims is disclosed. The Examiner states that this genus comprises a

YGGFM peptide, a cinnamoyl carrier, and a -C6-C8 linker moiety. However, there is nothing in the specification that limits the claims as such.

In fact, the specification makes clear that any number of peptides can be utilized within the general formulation of the invention (See, with regard to US 2004/0186058, for example, [0011-0014], [0041-0048]); the carrier can be any of several chemical moieties (See, for example, [0013-0014], [0018]); and the linker can be a -C6 to -C16 lipidic chain, an 8-amino-3,6-dioxaoctanoic acid and polymers thereof, a natural peptide, a pseudopeptide of less than 4 residues for example, Gly-carba-Gly, a peptide mimic of less than 4 residues, palmitoyl, aminooctanoyl, hydroxyvaleryl-aminoactanoyl, and combinations thereof (See, for example, [0011], [0015-0017], [0041-0048], and Example 2). As such, the specification adequately describes the entire genus such that a person of skill in the art would appreciate that the Applicants were in possession of the entire scope of the claims at the time of filing the instant application.

The Applicant points out that the embodiment cited by the examiner is merely an exemplary embodiment; not the only embodiment described by the specification and encompassed by the claims. Moreover, the language cited by the Examiner for the proposition that only a C6-C8 linker is described or enabled is incorrect and taken out of its proper context. Rather, the specification teaches that in one exemplary embodiment, "the linker species is bound to the carrier through a C6 or C8 acidic moiety." As such, the Examiner's statement (provided above) is not even referring to one of the linkers described by the invention but merely a potential means of linking the linker moiety to the carrier moiety.

The specification is written for a person of ordinary skill in the art at the time of the invention and, as such, can and preferably does omit that which is known in the art. Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). It is also axiomatic that an Applicant need not provide and example of every embodiment within the scope of the claims in order to satisfy the written description requirement. In other words, an inventor may submit prophetic examples. Union Oil Co., at 997 (a claim's scope does not run afoul of section 112 simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.). Even in an unpredictable art, patent applicants are not required to disclose every species encompassed by their claims. In re Vaeck, 947 F.2d

488, 496 (Fed. Cir. 1991); In re Wallach, 378 F.3d 1330, 1334 (Fed. Cir. 2004). In this case, the skill in the art is very high and the techniques needed to make the invention were, even at the time of filing, routine in the art. Also, at the time of filing the instant invention, a variety of therapeutic peptides were known that could be utilized in the composition of the invention. As such, the invention is not intended to be limiting to any exemplary embodiments described in the specification. Therefore, a person of skill in the art at the time of the invention would understand that the inventors were in possession of the entire scope of the invention.

Similarly, enablement does not mean that "the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments...." AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Given the teachings of the present specification, and the level of the skill in the art, the ordinary skilled artisan could easily make and use therapeutic compositions as recited in the claims. As such, it is unnecessary to provide detailed examples of every embodiment encompassed by the claims. See, Ex parte Kubin, Apeal 2007-0819 (BPAI May 31, 2007) ("the amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art."). Accordingly, the entire scope of the claims is sufficiently described and enabled under 35 USC 112, first paragraph.

The present invention is based upon the discovery that the bioavailability of therapeutic peptides can be improved by linking the therapeutic peptide with a particular class of carrier moieties. This aspect is described and claimed in the parent applications 09/844,426, now abandoned; 10/237,254; now abandoned; and 10/505,903, now US Patent 6,908,900 (the "'900 patent"). As indicated above, the beneficial effect is not limited by the particular peptide employed in the construct, however, peptide size appears to play a role in mediating the ability of the carrier to improve the bioavailability of the peptide drug.

The parent of the present Application, i.e., the '900 patent, describes pharmaceutical compositions in which a carrier is bound to a therapeutic peptide to enhance bioavailability. The '900 patent also describes the inclusion of a linker bound to the carrier and therapeutic peptide to

allow for additional steric freedom. The carrier-linker-peptide embodiment is the subject of the instantly pending claims. As indicated above, the instant claims as well as the claims of the '900 patent are not limited by any particular peptide, but only by the size of the peptide. Therefore, just as the scope of the claims of the '900 patent are fully described and enabled; the full scope of the instant claims is also fully described and enabled to a person of skill in the art at the time of the invention. In addition, the Applicant notes that a Terminal Disclaimer has already been filed in view of the '900 patent because the instant claims are subsumed by the claims of the parent. For at least these additional reasons, the present rejections should be withdrawn.

The Examiner also rejects the claims based on the recitation of "derivatives" of the carrier and linker. The Applicant notes that in order to expedite the allowance of the instant claims, the claims were previously amended by deleting reference to "derivatives." As amended, the entire scope of the claims is sufficiently described under 35 USC 112, first paragraph, and therefore, this rejection is moot.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

**CONCLUSION**

Applicant honestly believes that all aspects of the present Office Action have been sufficiently addressed and submits that the present application is now in condition for allowance, and notice to that effect is respectfully requested.

If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Applicant believes that fees for a two-month extension of time are due in association with entry of the current response. As such, the Commissioner is hereby authorized to charge Deposit Account No. 50-3569 in the amount of $230.00 for a two-month extension of time for a Small Entity. However, if any fee has been inadvertently overlooked and is required, Commissioner is hereby authorized to debit any fee due or credit any overpayment to Deposit Account No. 50-3569.

Respectfully submitted,

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